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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/099,823	06/19/1998	PATRICIA A. BILLING-MEDEL	6120.US.P1	7897

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/11/2002

2/4

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/099,823

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 02 July 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.


NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 50-74.Claim(s) withdrawn from consideration: 17-29, 31, 32, 34, 36-37, 43-44.

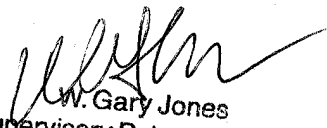
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____



Continuation of 5. does NOT place the application in condition for allowance because:

The request for reconsideration states the purpose of Section 101. This assertion is well established. The request further asserts that the specification at the time of filing disclosed a specific and substantial utility for the claimed invention, i.e. "provide information for detecting, diagnosing, staging, monitoring, and prognosticating, preventing or treating of or determining the predisposition to disease and conditions of the breast, such as breast cancer". As discussed in the enablement rejection of record, the nucleic acids of the invention are found in both normal and cancer tissue from the breast in addition to testis, lung tissues. Therefore, the nucleic acids do not appear to be predictably correlated with detection of breast cancer.

The response further asserts that the evidence provided in their previous response is supportive that the nucleic acids belong to the lipocalin family. Since this asserted "utility" was not originally presented in the specification, the argument is not persuasive. Moreover, since the references are post-filing date, the applicant can not rely on well-established utility to establish utility. Therefore, the BLAST comparison search to NM01582 (available November 2000) does not support the utility of the instant invention. The knowledge that lipocalins were a "family of molecules which are known by those of ordinary skill in the art to play an important role in cancer onset and progression" was not well established at the time of filing. Therefore, there is no well-established utility for the claimed nucleic acids and methods.


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600